

REMARKS/ARGUMENTS

Claims 1-55 are currently pending and under examination. With entry of the present Amendment, claims 17 and 26 have been amended to correct the minor errors noted by the Examiner in the Office Action, and claims 36 through 55 have been canceled without prejudice or disclaimer. In addition, Figure 1, together with the brief description of Figure 1 in the specification, have been amended in accordance with the Examiner's suggestion in the Office Action. The foregoing amendments relate to formal matters and, thus, no new matter has been introduced.

Applicant acknowledges, with appreciation, the Examiner's statement that claims 1-16, 18-23, 25-30 and 35 are allowable (*see*, page 9 of the Office Action).

In the Office Action, the Examiner objected to the Oath/Declaration as being defective and to Figure 1, as originally filed, for allegedly failing to show the mechanism of regulation of gene expression as described in the specification (*see*, page 2 of the Office Action). Claims 26-35 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claim 17 and 26-35 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claims 24, 32-34 and 48-55 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled. For the reasons set forth herein, each of the Examiner's rejections is overcome.

Objection to the Oath or Declaration

In the Office Action, the Oath/Declaration was objected to as being defective for failing to "identify the city and either state or foreign country of residence of each inventor." However, the Office Action further states that: "[t]he residence information may be provided on either an application data sheet or supplemental oath or declaration" (*see*, page 2 of the Office Action).

Applicant respectfully submits that the residence information for Dr. Murali Ramachandra, the sole inventor of the above-referenced patent application, was provided on the application data sheet (ADS) that was filed in the USPTO concurrently with the above-

referenced patent application. As such, Applicant believe that the Oath/Declaration in not defective. If, however, this is not sufficient and the Examiner requires a Supplemental Oath/Declaration, Applicant would be more than happy to provide the Examiner with such Supplemental Oath/Declaration.

Objection to the Drawing

In the Office Action, Figure 1 was objected to as failing to show the mechanism of regulation of gene expression as described in the specification (*see*, page 2 of the Office Action). The Examiner has indicated that this objection can be overcome by designating the lines with arrowheads as "mRNA." In addition, the Examiner requests that the two parts of the figure be labeled FIG. 1A and FIG. 1B.

In order to expedite prosecution, Applicant has amended FIG. 1 to explicitly designate that the lines with the arrowheads are "mRNA," and to designate the two parts of Figure 1 as FIG. 1A and FIG. 1B. In view of the amendments to Figure 1, this objection is overcome.

Rejection Under 35 U.S.C. § 101

Claims 26-35 have been rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter due to the recitation of "cells" containing the claimed nucleic acid vectors (*see*, page 3 of the Office Action). The Examiner has indicated that this rejection can be overcome by amending the claims to recite "an isolated cell. . . ." (*see*, page 4 of the Office Action).

In order to expedite prosecution, Applicant has amended independent claim 26 to recite "an isolated cell. . . ." As such, claims 27-35, which are dependent on claim 26, are also now directed to "an isolated cell. . . ." In view of the amendment to claim 26, the Examiner's rejection is rendered moot. Accordingly, Applicant urges the Examiner to withdraw this rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 17 and 26-35 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In making this rejection, it was noted that claim 17 recites “nucleic” instead of “nucleic acid,” and claim 26 recites “cell” instead of “isolated cell” (*see*, page 3 of the Office Action.) The Examiner indicated that this rejection can be overcome by amending these claims to correct these issues.

In order to expedite prosecution, and as previously explained, Applicant has amended claim 17 to recite “nucleic acid” and claim 26 to recite “an isolated cell.” In view of the amendment to claims 17 and 26, the Examiner’s rejection is rendered moot. Accordingly, Applicant urges the Examiner to withdraw this rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 24, 32-34, 36-47 and 48-55 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled.

In order to expedite prosecution, Applicants have canceled, without prejudice or disclaimer, claims 48-55. Applicants expressly reserve the right to pursue claims equal or greater scope to claims 48-55 in this application or in a related application.

With respect to claims 24 and 32-34, Applicants respectfully submit that the specification teaches how to make and use the claimed invention, *i.e.*, the claimed expression vectors and the claimed isolated cells, *without* undue experimentation. Clearly, there is no doubt that the specification teaches how to make the claimed expression vector and cells. Moreover, as explained in the specification, expression vectors comprising the nucleic acid of claim 1 as well as cells comprising the nucleic acid of claim 1 can be used to regulate expression of a gene *in vitro*, *in vivo* and *ex vivo*. In fact, as acknowledged by the Examiner in the Office Action, “it would not be problematic to use the molecular switch *in cells* in the laboratory” (*see*, page 8 of the Office Action). Moreover, the background section of the specification provides examples of the use of “molecular switches” to regulate gene expression *in vivo*.

In the Office Action, the Examiner mentions a number of problems associated with gene therapy as support for the non-enablement rejection. However, the enablement of the presently claimed composition-of-matter does not hinge on whether every aspect of gene therapy has been perfected. Again, as acknowledged by the Examiner in the Office Action, "it would not be problematic to use the molecular switch *in cells* in the laboratory." The ability of the presently claimed molecular switches to regulate expression of a gene is more than sufficient to support the enablement requirement of 35 U.S.C. § 112, first paragraph.

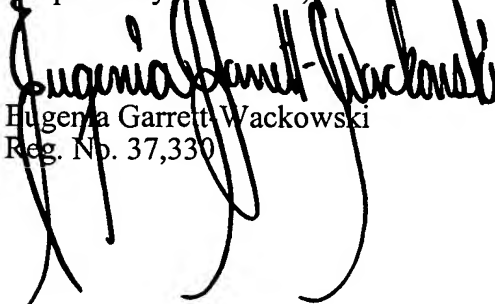
In view of the foregoing, Applicants respectfully submit that the expression vector of claim 24 and the isolated cells of claims 32-34 are fully enabled by the specification as originally filed. Accordingly, Applicants urge the Examiner to withdraw this rejection and to allow claims 24 and 32-34 together with claims 1-23, 25-30 and 35.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,


Eugenia Garrett Wackowski
Reg. No. 37,330

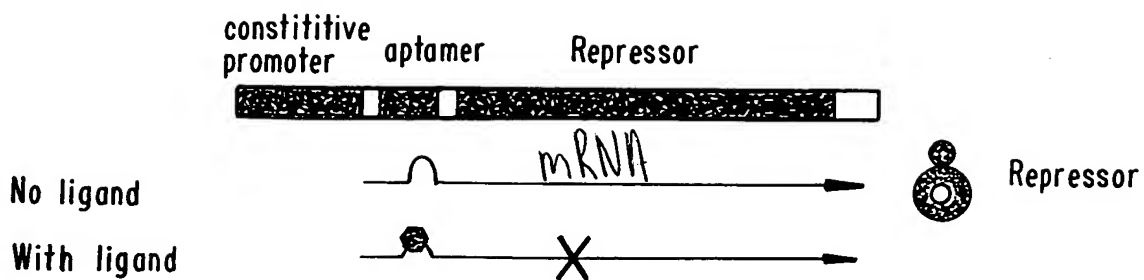
TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300
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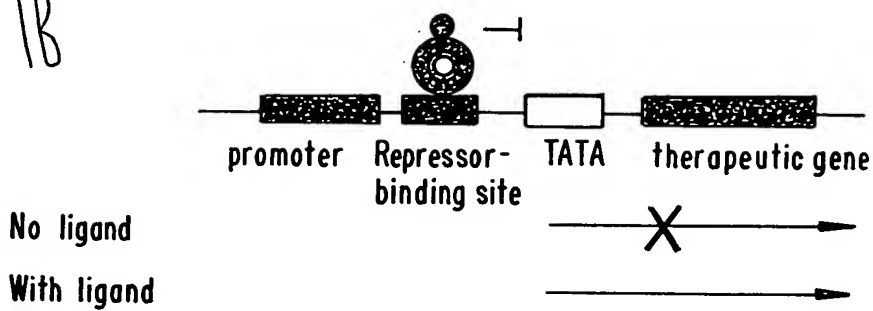


FIG. 1.

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